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September 7, 2011

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of a 5-Day Repeated Intravenous Injection Study with Hexamoll DINCH, IUPAC Name: 1,2-Cyclohexane dicarboxylic acid, di(isononyl)ester (CAS No. 47419-59-0)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a 5-Day Repeated Intravenous Injection Study with Hexamoll DINCH, IUPAC Name: 1,2-Cyclohexane dicarboxylic acid, di(isononyl)ester (CAS No. 47419-59-0) conducted by BASF SE, Ludwigshafen, Germany.

Control (Intralipid 20%) and test article (Intralipid 20% plus DINCH) were administered once daily for five consecutive days by intravenous infusion over 10 minutes. Daily average daily dose per low, mid, and high dose animals was 61.25, 105, and 268.75 mg/kg, respectively.

All animals survived and appeared normal throughout the study. No statistical differences for body weight at each time point by sex were observed between control and test article groups. Although there were a few statistical differences observed between control and test article groups for various hematology and clinical chemistry parameters, no toxicological trends were observed and the differences were not considered toxicologically or biologically significant. There were some statistical differences in organ weights between control and test groups.

At necropsy, petechiae in the lungs was prevalent in several Day 5 test article animals (all groups), but only observed in one Day 5 control article animal. The Day 5 necropsy observations were considered predominantly related to test article administration rather than the test substance itself. Only selected tissues were microscopically evaluated. Hemorrhage and vacuolated interstitial histiocytes in the lungs and cytoplasmic vacuolation involving the reticuloendothelial cells of the spleen and Kupffer cells of the liver were observed in rats administered the test article intravenously for 5 consecutive days; the incidence of these lesions was lower for the low and mid-dose groups, and after 5 days of recovery. These lesions are thought to reflect an elimination process of the hydrophobic test substance; indeed, these findings have been described by others following intravenous infusion of lipids into humans and experimental animals (Koga *et al.*, *Ann. Surg.* 181: 186-190, 1975; Stuart and Smith, *J. Pathol.* 115: 63-71, 1975; Penco *et al.*, *Nutrition* 10:26-31, 1994; Driscoll *et al.*, *Clin. Nutr.* 24: 105-113, 2005)

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CONTAINS NO CBI

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please contact the undersigned at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Expertise
North America

/

Hexamoll DINCH_082511 Letter.doc

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